with the manufacturer; independent "professional trustees" would publish non-binding "appraisals" of drugs to guide doctors and patients; and patients would have greater access to the courts to take action for negligence where they suffer harm from drug treatment.

Green's criticisms have some merit. A regulatory authority inevitably imposes some delay while submissions are critically reviewed, but, as Green admits, the bureaucratic delays in Britain are slender compared with those in the United States, where commentators have looked enviously at the relative speed with which new drugs reach the market in Britain.[3,4] Green is also right in pointing out that the development time for new drugs to reach the market has increased substantially over the past 25 to 30 years, but he is wrong to conclude that the increase is necessarily caused by the demands of regulatory authorities.[5] In truth drug development has become much more complex during the past 25 years because of advances in pharmacology, toxicology, and clinical medicine. And, although preclinical toxicology is unable to detect all the possible hazards that might occur during widespread use with a new compound, modern techniques ensure that most type A reactions are recognised by the time a new drug is marketed[6]; with our current arrangements tragedies such as the sulphonilamide and Stalinon disasters are unlikely to recur. A better solution to the adverse economic consequences of protracted development times might be to extend the patent life of new drugs.

Whether or not the Committee on Safety of Medicines takes "sufficient" account of risks and benefits when making recommendations is more difficult to confirm or refute. For, while benefits and risks can each be scientifically investigated and measured, the trade off between them is usually based on judgment. In circumstances where a drug either cures or produces a worthwhile remission in an otherwise lethal or untreatable condition the judgment is easy: the decision to license zidovudine (Retrovir), despite its known toxicity, for treating the acquired immune deficiency syndrome is a recent example. Risk-benefit assessments are also straightforward where a product's safety profile is clearly out of proportion either with the natural course of the disease for which it is indicated or with other treatments.

Trade offs are less easy for drugs offering modest symptomatic relief for the many at the expense of serious toxicity for the few. Such fine judgment is, of course, part of the daily practice of medicine, and membership of the Committee on Safety of Medicines is drawn predominantly from among doctors engaged in clinical practice.[7] Without entering into metaphysical arguments about whether the committee's judgments are "sufficient," it is most unusual for drugs that are licensed in Britain to remain unavailable in other developed countries for long. By contrast, there have been instances where drugs denied licences in Britain have been associated with serious problems after marketing elsewhere in the world. The British regulatory system has a good record and international reputation.

The prospect of replacing our licensing procedures with a system based on legal tort would have little appeal to the pharmaceutical industry, doctors, pharmacists, or patients. Leaving aside the real difficulties in establishing causation (as opposed to association) in suspected cases of iatrogenic disease, much of the population—that is, those too wealthy to qualify for legal aid but too poor to pay what may be enormous costs—would be unable even to contemplate the risks of taking an action. Many cases, moreover, would result in legal wrangles about apportioning responsibility among manufacturer, prescriber, and dispensing pharmacist. The only beneficiaries would, I suspect, be lawyers and clinical pharmacologists (retained as expert witnesses for both plaintiff and defendants). The absence of a statutory licensing mechanism would also remove the present basis for controls on promoting and advertising medicines. The lessons from history,[1] and from those developing countries which lack effective drug regulatory controls,[8] would have to be learnt again.

There is one practical problem with deregulation which Green ignores. The Treaty of Rome aims at creating a complete "internal market," including pharmaceuticals, within the European Community. Since 1965 a series of directives has been agreed between member states harmonising the broad criteria for granting licences—that is, quality, safety, and efficacy—and the scientific data to support marketing applications.[9] Although member states retain the power to make their own decisions, Britain could not move unilaterally down the road Green advocates without abrogating its obligations under European Community law.

There may well be a need for evolutionary changes in the administrative arrangements covering drug regulation. Indeed, the Secretary of State for Social Services has set up an inquiry to review the arrangements for processing licence applications. In due course the Medicines Act itself will no doubt need revision to take account of changing scientific, political, and social circumstances. The deregulatory option, however, is in the interests of neither producers, prescribers, nor patients—and it isn't really possible.

MICHAEL D RAWLINS

Professor of Clinical Pharmacology,
Wolfson Unit of Clinical Pharmacology,
The University,
Newcastle upon Tyne NE1 7RU

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Correction

Glasnost on pesticides

We regret that an error occurred in the article "Glasnost on pesticides" (9 January, p 81). In the last sentence of the penultimate paragraph the word patents was misprinted as patients. The sentence should have read: "Perhaps with adequate protection of patents a fair arrangement for the release of data could be agreed."